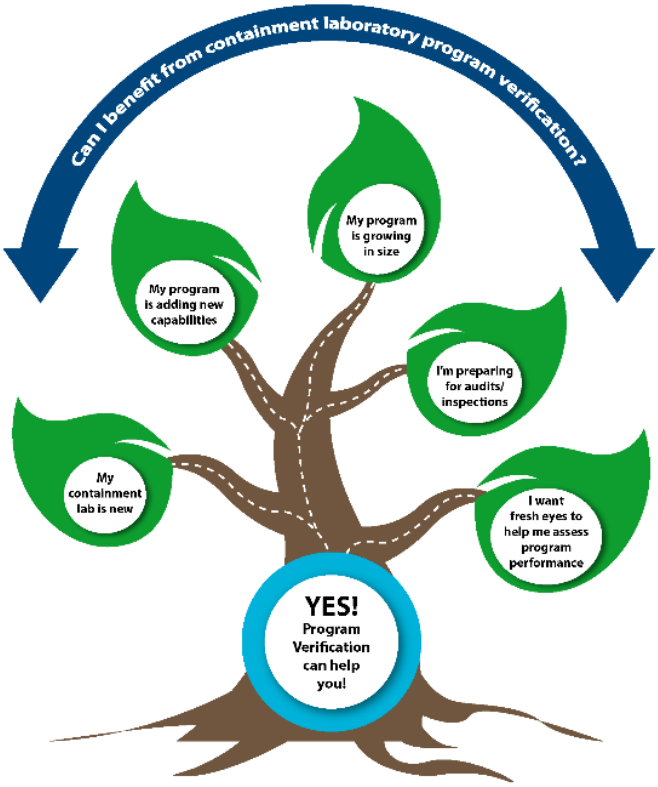
Tending Your Containment Laboratory Biosafety Program

Biosafety programs are dynamic, ever-evolving constructs.

Even a mature program continues to grow and adapt as the landscape of laboratories, projects, and regulatory requirements it serves changes. Growth alone, however, does not guarantee that the biosafety program provides the most effective coverage possible. Whether you are in the process of planting the roots of your program, growing your program to cover new capabilities or projects, or tending a mature program, it is important to periodically verify that the program is adequately meeting the needs of the laboratory personnel and overall institutional requirements while complying with all relevant regulations and guidelines.



What is containment laboratory program verification?

What does it mean to verify a program? Merriam-Webster defines verify as "the establishment of the truth, accuracy, or reality of". Biosafety programs, particularly those whose scope includes containment laboratories, are rooted in a variety of regulations, guidelines, and standards that help define the core of the program's work. The shape of the program, however, is defined by the work being performed in the laboratory and the needs of the institution. Verification of a biosafety program involves assessing whether the laboratory operations are adequately supported by the program in a manner that meets or exceeds the applicable regulations, guidelines, and standards.

What is the difference between containment laboratory validation and containment laboratory program verification?

Containment laboratory *validation* typically focuses primarily on ensuring that the engineering features of the laboratory or facility perform to the appropriate standards or specifications. Validation most commonly occurs after construction or renovation activities are completed, as well as on at least an annual basis. Containment laboratory *verification* focuses more on the human aspect of the equation—are the necessary plans, policies, and procedures in place to meet the program's needs and requirements? Are *all* relevant personnel, from the laboratorians to the facility operations staff to the

custodial providers, appropriately engaged with the biosafety program and comfortable performing their particular biosafety-related roles and responsibilities?

How do I know if my containment laboratory program needs to be verified?

The most dramatic indicator that a containment laboratory program needs to be verified is when a laboratory incident or inspection highlights a previously-unknown gap in practice, policies, and/or procedures. Reactive program assessment as part of the time and resources spent resolving an event can lead to overly-stringent corrective measures being put in place, which may damage relations between the biosafety program and the end users. Proactive verification can help reduce the likelihood of such an event, particularly when judiciously timed. For example:

- *When an institution is adding high containment laboratory capability for the first time*. The demands on a biosafety program when first standing up a high containment laboratory can be significant. Containment laboratory program verification can help identify and prioritize biosafety program needs and requirements so that the containment laboratory program grows from the strongest possible foundation.
- *When a program is adding new capabilities*. What happens when laboratory users want to bring in new technologies to the containment laboratory? Or plan to shift from small scale to large scale operations? Containment laboratory program verification can help ensure that the biosafety program adapts to support new capabilities.
- *When a program is growing in size.* The programmatic needs of a single containment laboratory versus multiple containment suites can vary dramatically. Containment laboratory program verification can help identify the right-size biosafety solutions for expanding containment laboratory programs.
- *When preparing for audits and inspections.* Significant audit or inspection findings can delay or temporarily halt containment laboratory research and diagnostic operations. Containment laboratory program verification can help identify gaps and mitigation strategies as part of the audit or inspection preparation process.

Even when a mature containment laboratory program is not undergoing significant changes in size or scope, laboratory activities, regulations, standards, and guidelines all evolve over time. Periodic containment laboratory program verification can help ensure that the biosafety program remains relevant and current with even the more gradual shifts.

Why involve a third party for containment laboratory program verification?

Containment laboratory program verification requires time and expertise. In many institutions, the Biosafety Program staff are already working at full capacity. Sometimes capabilities are being added that the Biosafety Program staff lack the expertise to fully address themselves. In these cases, involving a third party in the verification exercise can help the Biosafety Program to meet its timelines and objectives without neglecting existing obligations.

MRIGlobal is here to help!

MRIGlobal's Global Biological Engagement Program has spent decades collaborating with universities, private industry, and US government to develop tailored verification programs for assessing containment laboratory biosafety programs. With more than 60 years of experience in scientific research, including 20 years managing high containment laboratories and vivariums, MRIGlobal has earned a reputation for delivering services with excellence in quality, integrity, and safety.

Contact Us with Your Program Needs

Dr. Sharon E. Altmann
Ph.D., RBP, CBSP
Senior Scientist
Global Health Surveillance & Diagnostics
saltmann@mriglobal.org
240-361-4036

Specialties

- Biosafety and biosecurity
- High containment laboratories
- Training program development & execution
- Research program assessment

Scott Shearrer
Senior Engineer
Global Biological Engagement
sshearrer@mriglobal.org

Specialties

- Biosafety/Biosecurity/High Containment
- Laboratory Start-up
- Biocontainment Equipment

Lolly Gardiner
MBA, RBP, SM (NCRM), RBP
Program Manager, BS&S
Global Bio Engagement
lgardiner@mriglobal.org
720-518-7358

Specialties

- Biological Safety and Security
- Laboratory Start-up
- Program Management
- Staff Training and Development